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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 22, 2004

Mr. Albert Haier, Partner
Beck Farms, LP
28 Red Mill Road
Freeville, New York 13068-9563

NYK-2004-24

Dear Mr. Haier:

On April 7, 8, 21, and 22, 2004 U.S. Food and Drug Administration investigators conducted an inspection at your farm located in Freeville, New York. This inspection confirmed that you offered an animal for sale for food that was adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused an animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a) (5) of the Act because the drugs were used in a manner that does not conform to their approved use or the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530).

On or about February 19, 2004, you offered for sale a cow identified with farm tag [redacted] and ear tag [redacted] for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.19 parts per million (ppm) penicillin in kidney tissue

A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (21 CFR 556.510). The presence of this drug in excess of the established tolerances in the kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. For example, there are no records for the treatment of the above cow with penicillin. Foods from animals held under such conditions are adulterated under Section 402(a) (4).

You are also adulterating the drug [redacted] brand of penicillin G procaine injectable suspension within the meaning of Section 501(a) (5) of the Act. You used this drug in cattle at a higher than labeled dosage. Because your extra label use of [redacted] was not in compliance with 21 CFR Part 530, the drug is unsafe to use under Section 512(a) of the Act.

This is not an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

We note that this is not the first residue associated with your farm. On or about July 15, 2003, you offered for sale a cow identified with farm tag [redacted] and ear tag [redacted] for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 1.22 ppm gentamicin in kidney tissue. There is no tolerance established for residues of gentamicin in edible tissues of cattle (21 C.F.R. 556.300).

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Laurence D. Daurio, Compliance Officer, at the above address.

Sincerely,

Jerome G. Woyshner
District Director

cc: Ronald Beck & Russell Beck
Partners
Beck Farms LP
28 Red Mill Road
Freeville, New York 13068-9563